UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BTG INTERNATIONAL LIMITED, et al., Plaintiffs, **v.** **ACTAVIS LABORATORIES FL, INC., et al.,** Defendants.	Civ. No. 15-cv-5909 (KM)(JBC) **OPINION** **(*Markman* Patent Claim Construction)**

MCNULTY, U.S.D.J.:

This Hatch-Waxman litigation arises out of the defendants' submissions of Abbreviated New Drug Applications ("ANDAs") with Paragraph IV certifications to the United States Food and Drug Administration (the "FDA").[1] The plaintiffs, BTG International Limited ("BTG"), Janssen Biotech, Inc., Janssen Oncology, Inc. ("Janssen Oncology"), and Janssen Research & Development, LLC (collectively, "Plaintiffs"), are the owners or exclusive licensees of two patents on a branded drug, ZYTIGA® (abiraterone acetate) Tablets ("ZYTIGA®"): United States Patent Nos. 8,822,438 (the "'438 patent") and 5,604,213 ("the '213 patent"). The defendants are generic drug companies who seek to engage in the commercial manufacture, use, offer for sale, or sale of a generic version of the plaintiffs' drug.

The plaintiffs claim that the defendants have infringed by submission of their ANDAs, and that the defendants' manufacture or sale of a generic version

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[1] A Paragraph IV certification submits that the patent covering the branded drug currently being marketed is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the proposed generic drug product for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* Defendant Actavis Laboratories Fl, Inc.'s Answer and Counterclaims to Plaintiffs' First Amended Complaint for Patent Infringement (ECF No. 85).

of the drug will infringe the '438 and '213 patents.[2] Defendants have denied infringement and counterclaimed for declaratory judgment that Plaintiffs' patents are not infringed or are invalid.

This Opinion pertains only to construction of the '438 patent, entitled "Methods and Compositions for Treating Cancer," which the USPTO issued on September 2, 2014. That patent covers all FDA-approved indications of ZYTIGA®, a therapy that has demonstrated efficacy in extending the lives of advanced prostate cancer patients.[3] In connection with preparations for a

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[2] BTG owns the '213 patent and Janssen Oncology owns the '438 patent. The Janssen plaintiffs are the exclusive licensees of the '213 patent. (*See* Amended Complaint (ECF No. 47) ¶¶ 57–60.) Currently pending before this court is a separate motion to amend the complaint seeking to add patent infringement claims against certain of the Defendants as to U.S. Patent No. 8,236,946 and U.S. Patent No. 8,389,714, both also owned and/or licensed by the plaintiffs, but neither of which is at issue in this Opinion. (*See* ECF No. 204.)

Also pending is a motion to Set a Hearing and Correct Inventorship of the '438 patent by Plaintiffs, with which Plaintiffs filed a proposed Second Amended Complaint (No. 176) that seeks to add an additional inventor to the '438 patent and to add BTG as a plaintiff with respect to counts asserted and recovery sought under the '438 patent. Thus, BTG is not a plaintiff with respect to the counts asserted under the '438 patent at this time.

[3] For purposes of this opinion, citations to the record will be abbreviated as follows:

- '438 patent = Copy of U.S. Patent No. 8,822,438, Exhibit 1 to the Declaration of Brendan F. Barker in Support of Defendants' Claim Construction Brief (ECF No. 210-3)
- Pl. Br. = Plaintiffs' Opening Claim Construction Brief (ECF No. 209)
- Def. Br. = Defendants' Opening Claim Construction Brief (ECF No. 210)
- Pl. Resp.= Plaintiffs' Responsive Claim Construction Brief (ECF No. 220)
- Def. Resp. = Defendants' Responsive Claim Construction Brief (ECF No. 221)
- Barker Decl. = Declaration of Brendan F. Barker in Support of Defendants' Claim Construction Brief (ECF No. 210-2)
- Barker Resp. Decl. = Declaration of Brendan F. Barker in Support of Defendants' Responsive Claim Construction Brief (ECF No. 221-1)
- Fruehauf Decl. = Declaration of John P. Fruehauf, M.D., Ph.D. on Claim Construction (ECF No. 210-1)
- Miller Decl. = Declaration of Keith J. Miller, Esq. in Support of Plaintiffs' Opening Claim Construction Brief (ECF No. 209-1)

Markman hearing, it emerged that the key disputed terms are "treatment" and "treating". For the reasons discussed below, the court adopts the plaintiffs' proposed construction of the terms "treatment" and "treating".

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

The parties' dispute as to construction of the '438 patent is a narrow one: what is the meaning of the terms "treatment" and "treating" in the claimed methods? Claim 1, the only independent claim of the '438 patent, states:

> 1. A method for the **treatment** of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

('438 patent, 16:16–20 (emphasis on disputed term).) "Treatment" is the only disputed term that appears in claim 1. The parties also include the term "treating," however, because "treating" appears in their proposed joint construction of the term 'therapeutically effective amount." The parties agree that a "therapeutically effective amount" means "an amount effective for **treating** cancer." (*See* Def. Br. 5 n.4 (emphasis on disputed term).)[4]

Plaintiffs submit that "treatment" and "treating" must be given a restrictive construction that encompasses only "reducing the growth and spread of cancer cells." (Pl. Br. 2) Defendants, on the other hand, argue for a more inclusive construction that covers "all of the uses and therapeutic benefits known" when this method for treating prostate cancer in patients was invented. Defendants' more inclusive construction would encompass

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- MJCC = So-Ordered Letter Modifying Joint Claim Construction and Prehearing Statement (ECF No. 208)

[4] Additionally, the parties agree that the preamble of claim 1, on which claims 2-20 of the '438 patent depend and reads "A method for the treatment of a prostate cancer in a human," is "limiting, and limits the claims to the treatment of a prostate cancer in a human." They agree that "refractory prostate cancer" means "Prostate cancer that is not responding to an anti-cancer treatment or prostate cancer that is not responding sufficiently to an anticancer treatment. Refractory prostate cancer can also include recurring or relapsing prostate cancer." And, they agree that "therapeutically effective amount" means "an amount effective for treating cancer." (MJCC 2.)

treatments targeted at reducing the actual prostate cancer, but also "reducing the pain associated with prostate cancer and replacing the normal production of glucocorticoids that is blocked when patients are given CYP17 inhibitors." (Def. Br. 1.) To simplify, Plaintiffs say that the '438 patent covers only a treatment for shrinking and/or killing actual cancerous tumor cells; Defendants agree that it covers this, but say the patent *also* covers pain relief and glucocorticoid replacement.

To reflect their positions, the parties propose the following constructions of "treatment"/"treating":

- Plaintiffs propose: "the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer."

- Defendants propose: "**including** the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer."

(*See* MJCC; ECF Nos. 231, 232 (October 21, 2016 letters from parties reflecting further revision to joint construction)(emphasis added).) The proposed definitions are identical, except for the word "including" which appears at the beginning of Defendants' proposal.

The '438 patent itself defines the disputed terms in the specification as follows:

> As used herein, and unless otherwise defined, the terms "treat," "treating" and "treatment" include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer.

('438 patent 3:46–50 ("Definitions" section).)[5]

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[5] Plaintiffs have informed this court they "have no objection to the Court's adopting this express definition from the patent with the word 'include,' so long as the Court clarifies that the word 'include' is used in this definition in its restrictive sense." (October 21, 2016 Letter from Justin T. Quinn (ECF No. 232).)

A bit of scientific background may assist in clarifying the issues. The parties generally agree as to the following description of the treatment of prostate cancer generally and specifically with ZYTIGA®. Prostate cancer is the uncontrollable proliferation of prostate cells. Male sex hormones called androgens promote the growth of prostate cancer cells, so a common treatment for prostate cancer is androgen deprivation therapy ("ADT"). ADT aims to lower the body's production and circulation of testosterone, a naturally occurring androgen, in the body. The drug abiraterone acetate belongs to a class of drugs known as CYP17 inhibitors, which block production of testosterone in a patient's adrenal glands. CYP17 inhibitors, however, also block production of other steroids and hormones, which can lead to serious side effects. To reduce such side effects, patients receiving this class of drugs often receive steroid replacement therapy. Steroid replacement therapy often involves administration of prednisone, a synthetic type of a subclass of steroid called a glucocorticoid. Steroids like prednisone inhibit the growth of cancer cells; they also provide pain relief, or palliative treatment, to prostate cancer patients. (*See* Pl. Br. 2–3; Def. Br. 3–4.)

ADT is not considered a cure for prostate cancer because in most patients, it eventually loses effectiveness in inhibiting tumor growth. Prior to the invention described in the '438 patent, prostate cancer not responsive to ADT (known as or metastatic castration-resistant prostate cancer ("mCRPC"), had few treatment options. The '438 patent invention—specifically the combination of therapeutically effective amounts of abiraterone acetate and prednisone, marketed as ZYTIGA®—has proven effective in extending the lives of patients with mCRPC. (*See* Pl. Br. 3–4; Def. Br. 3–4.)

Plaintiffs submit that the efficacy of the '438 patent invention was novel and surprising. At the time of the invention, they say, researchers doubted that an androgen-suppression drug like abiraterone acetate would be effective in castration-resistant prostate cancer patients; the prior art, moreover, did not suggest that prednisone could have any anti-cancer effect, alone or in combination with abiraterone acetate. (Pl. Br. 3.) Plaintiffs acknowledge that

glucocorticoids like prednisone had been used for palliation of chemotherapy-related side effects. But treatment with abiraterone acetate alone, say plaintiffs, did not cause such side effects, and therefore a person skilled in the art would not have seen a need to combine abiraterone acetate with a glucocorticoid. (*Id.* 4.)

The '438 patent is generally directed to methods for treating prostate cancer in humans. It discloses such methods as administration of a CYP17 inhibitor like abiraterone acetate in combination with another therapeutic agent such as an anti-cancer agent or steroid. The '438 patent identifies prednisone as one such therapeutic agent that can be combined with abiraterone acetate. (*Id.*)

Patent construction must of course precede any analysis of patent infringement. Therefore, on October 25, 2016, I convened a *Markman* hearing to determine the meaning of the disputed terms. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976–79 (Fed. Cir. 1995) (en banc), *affd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). I have carefully considered the parties' written submissions and arguments. In this Opinion I set forth my construction of the disputed patent terms.

II. DISCUSSION

A. Standard of Review

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. In order to obtain a patent, the inventor must submit a written application providing (1) "a specification as prescribed by 35 U.S.C. § 112"; (2) "a drawing as prescribed by § 113"; and (3) "an oath or declaration as prescribed by § 115." *See* 35 U.S.C. § 111.

The patent's specification must contain:

> a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most

> nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Id. § 112.

The patent's "claims" round out the specification by "particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." *Id.* § 112.

> The function of claims is (a) to point out what the invention is in such a way as to distinguish it from what was previously known, i.e., from the prior art; and (b) to define the *scope of protection* afforded by the patent. In both of those aspects, claims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed . . . .

In re Vamco Mach. & Tool, Inc., 752 F.2d 1564, 1577 n. 5 (Fed. Cir.1985). Patent infringement analysis requires two steps: (1) determining the meaning and scope of the patent claims asserted to be infringed (i.e. "claim construction"); and (2) comparing the properly construed claims to the device or method accused of infringing. *See Markman,* 52 F.3d at 976; *RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1266 (Fed. Cir. 2003) ("An infringement analysis involves two steps in which the court first determines the correct claim scope, and then compares the properly construed claim to the accused method or device to determine whether all of the claim limitations are present either literally or by a substantial equivalent."). Here, we are concerned only with step one, which involves "a matter of law exclusively for the court." *Markman,* 52 F.3d at 977.

> A fundamental principle of claim construction is that patent claims must have the same meaning to all persons at all times, and that the meanings of the claims are determined and fixed at the time the [PTO] issued the patent. The purpose of a *Markman* hearing is for the court and the parties to settle conclusively on the interpretation of disputed claims. Indeed, the need for uniformity of claim construction and concerns about fairness to competitors inform the policy of reserving the claim construction function to the trial judge.

Novartis Corp. v. Teva Pharms. USA, Inc., 565 F.Supp.2d 595, 603 (D.N.J. 2008) (internal citations omitted). "When a court construes the claims of the patent, it is as if the construction fixed by the court had been incorporated in the specification, and in this way the court is defining the federal legal rights created by the patent document." *Markman*, 52 F.3d at 978 (internal quotations and citation omitted).

When construing claims, a district court should give the claim terms their "ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "Ordinary and customary meaning" however, is not limited to the understanding of the average person. Rather, it must be assessed from the standpoint of a hypothetical "person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."[5] *Id.* at 1313. That hypothetical person is sometimes abbreviated as a "PHOSITA" or "POSA"[6]

> [The] objective baseline from which to begin claim interpretation ... is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art. . . . Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Id.* (internal citations omitted); *see also Novartis Corp.*, 565 F. Supp. 2d at 604 ("Although an invention is defined by a patent's claims, they do not stand alone. Instead, claims are part of a fully integrated written instrument consisting principally of a written description of the invention, often referred to as the specification, and concluding with the claims. For that reason, claims must be read in view of the specification, of which they are a part.") (internal quotations and citations omitted).

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[6] For consistency with the parties' briefing, I will use the acronym "POSA" in this Opinion.

In some cases, the meaning of claim terms as understood by a POSA may be readily apparent, "even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips,* 415 F.3d at 1314. In other cases, however, the meaning is not so easily ascertained, and the court must look to the "sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *MBO Labs* 474 F.3d at 1329 (quoting *Phillips*, 415 F.3d at 1314). "Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips,* 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.,* 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

Those sources are not necessarily weighted equally; there is a hierarchy of relevance. Generally, the patent's "intrinsic evidence"—"the patent itself including the claims, the specification and, if in evidence, the prosecution history"—"is the most significant source of the legally operative meaning of disputed claim language." *Novartis,* 565 F. Supp. 2d at 603–04 (quoting *Vitronics Corp.,* 90 F.3d at 1582).

The patent's specification, "the single best guide to the meaning of a disputed term," should be consulted first. *Phillips,* 415 F.3d at 1317 (citing *Vitronics*, 90 F.3d at 1582). The specification may reveal "whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Novartis,* 565 F. Supp. 2d at 604 (quoting *Vitronics,* 90 F.3d at 1582). After consulting the specification, the court should review the patent's prosecution history, which also is "part of the 'intrinsic evidence' that directly reflects how the patentee has characterized the invention." *MBO Labs., Inc.,* 474 F.3d at 1329 (quoting *Vitronics,* 90 F.3d at 1317). The prosecution history includes statements made by the patentee during reexamination. *See Krippelz v. Ford Motor Co.,* 667 F.3d 1261, 1266

(Fed. Cir. 2012) ("A patentee's statements during reexamination *can* be considered during claim construction, in keeping with the doctrine of prosecution disclaimer") (citation omitted). Finally, if the specification and the patent's intrinsic evidence do not clarify the claim terms, the court may consult "extrinsic evidence"—testimony, dictionaries, learned treatises or other materials not part of the public record. *See Phillips,* 415 F.3d at 1317.

B. Analysis

1. The Specification

Plaintiffs argue that the dispute is resolved by the patent specification, which expressly defines "treatment" and "treating" with reference only to reducing the growth or spread of cancer, and not to additional therapeutic benefits. (Pl. Br. 8–9.) Plaintiffs correctly state that a patentee is entitled to act "as his own lexicographer" by clearly defining a claim term in the patent. This is so even where the claim term defined in the specification departs from its ordinary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("[T]he claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.").

Defendants affirm these legal principles, but seize on the word "include" in the definition of "treatment" and "treating":

> As used herein, and unless otherwise defined, the terms "treat," "treating" and "treatment" **include** the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer.

('438 patent 3:46–50 ("Definitions" section) (emphasis added).) They argue that "include," by its plain meaning, indicates an open-ended list and thus is not

limiting. Further, they contend, a non-limiting construction is consistent with the intrinsic record.[7]

a) Neighboring Language and Cited Text

Defendants contrast the verb "include" with the verb "means." "Means," they say, is the verb of choice for defining other terms in the specification. They argue that the patentees used "means" as a word of limitation, but used "include" to indicate open-endedness. (Def. Resp. 4–5.) In Defendants' view, "include" is equivalent to "including but not limited to," a phrase which also appears throughout the '438 patent specification. Plaintiffs, of course, take the opposite view. (*See* Pl. Resp. 7–8; Def. Resp. 4–5.)

Both parties rely on the hornbook canon of statutory construction directing me to interpret words so as to avoid rendering other words redundant.[8] Upon examination of the '438 patent, I am unconvinced that this canon of construction is of assistance in resolving this dispute. To begin with, the canon itself is far from definitive: "that the use of both terms in close proximity in the same claim gives rise to an inference that a different meaning should be assigned to each . . . is not conclusive; it is not unknown for different words to be used to express similar concepts, even though it may be poor drafting practice." *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d

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[7] For claim construction purposes, it does not matter, but I will say a word about a counterintuitive configuration in which the patent holder attempts to minimize the scope of its patent, while the would-be infringer attempts to expand it.

At the *Markman* hearing, Defendants acknowledged that their proposed broad construction is intended to advance a future challenge to the '438 patent's validity. Here, the issue, essentially, is whether unspecified benefits—palliative care and glucocorticoid replacement— are "included," so that, for example, the claim might be rendered invalid for obviousness in light of prior art describing the use of abiraterone acetate and/or prednisone for palliative care and/or glucocorticoid replacement.

[8] "When interpreting statutes, a court looks to the language of the statute and construes it according to the traditional tools of statutory construction, including certain well known canons of construction." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 987 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996); *see Ethicon Endo–Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1578 (Fed. Cir.1996) (avoiding construction that renders claim language mere surplusage); *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (same).

1367, 1373 (Fed. Cir. 2004). And those "other words" do not fall into a pattern that would permit the court to conclude that one construction or the other would render them redundant. The definitions section of the '438 patent specification uses three definitional formulations: "include, but are not limited to"; "means"; and "refers." (*See* '438 patent, cols. 4–5) It cycles through those words or phrases, however, with no discernible rhyme or reason. As for the concept of "including," the definitional section uses each of the following words or phrases one time each: "include" (the disputed word at issue, *id.* 3:47); "can include" (*id.* 4:5); "can also include" (*id.* 4:26–27). Once, in a more express disclaimer, the patent uses the phrase "should not be interpreted as being limited to" (*id.* 4:15–16). It does not really matter whether the ambiguity arising from these varying terms "is the result of sloppy drafting . . . [or drafting] with a degree of indefiniteness so as to leave room to later argue for a broad interpretation designed to capture later-developed competition." Either way, it is clear that scrutinizing this language "becomes a game of crystal ball gazing." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1335 (Fed. Cir. 2013) (Plager, J., concurring). I, at least, cannot discern that the drafters had any overarching rationale for choosing one term rather than the other in a particular case. Nor can I extract from the context a definition of the terms that would dictate either party's interpretation, or force a conclusion that one party's interpretation would render another term superfluous. In short, neither interpretation emerges from this process as a winner.

Defendants also contend that the specification explicitly "discloses the known use of prednisone to provide glucocorticoid replacement therapy when treating prostate cancer in patients who are administered CYP17 inhibitors." (Def. Resp. 5.) A POSA, say the Defendants, would understand that disclosure to mean that prednisone is being used in the treatment of prostate cancer "to provide not just its known anti-cancer benefits, but also its known palliative and glucocorticoid replacement benefits." (*Id.* 8).

I think the point is exaggerated at best. Certainly the patent nowhere uses the words "palliative and glucocorticoid replacement benefits." Here are

two pieces of evidence, however, that the defendants cite in support of their argument that a POSA would infer such a reference:

1. The specification discloses a practice of administering a CYP17 inhibitor such as abiraterone acetate "in combination with at least one additional therapeutic agent such as *an anti-cancer agent or a steroid.*" (Def. Br. 11 (citing '438 patent, Abstract, 1:7–12, 2:9–17, 5:9–13) (underline added)). Defendants contend that the "or" reflects a distinction between "anti-cancer agents" and "steroids." And that distinction, according to defendants, reveals that the patentees had in mind both cancer-targeted *and* therapeutic results as distinct purposes for their alleged invention. Defendants add that in the '438 patent's preferred embodiments, prednisone is listed as both a type of "anti-cancer agent" and as a type of steroid. (*See* Def. Br. 11–13.)
2. The Defendants focus on a citation in the specification to a pharmacological textbook by Goodman and Gilman. The citation appears at the end of a paragraph identifying types of steroids within the scope of the disclosure. Defendants characterize this "see, e.g." citation as incorporating the textbook into the specification by reference, and cite one chapter in the textbook (not specified in the citation) about steroids. The absence of any reference in that chapter to the use of steroids to attack cancer, they claim, would cause a POSA to interpret the specification language to encompass palliative and glucocorticoid replacement purposes. (*Id.* 12–13.)

Defendants urge that these two pieces of evidence, taken together, "confirm[] that steroids like prednisone were known to provide replacement therapy when a patient's normal production of glucocorticoids is impaired . . . ." And this conclusion, in turn, supports Defendants' proposed construction that the terms "treatment" and "treating" encompass more than anti-cancer effects. (*Id.* 13)

Plaintiffs point out that the specification never actually refers to use of a steroid for palliation. And it is significant, they say, that the specification

states: "The amount of the steroid administered to a mammal having cancer is an amount that is *sufficient to treat the cancer* whether administered alone or in combination with a 17α-hydroxylase/C17 20-lyase inhibitor." ('438 patent 10:19–24 (emphasis added).) At the *Markman* hearing, Plaintiffs submitted that if Defendants' construction had been intended, the claim would state: "A method for the treatment *of a patient* with prostate cancer," as opposed to "A method for the treatment *of a prostate cancer* in a human . . . ."

I agree with the Plaintiffs that the Defendants' parsing of the specification language is unconvincing. In my view, a POSA[9] would not interpret a "see, e.g." citation as incorporating by reference the entirety of a textbook for definitional purposes. Still less does the patent incorporate a particular chapter, not specifically cited, concerning steroids and their use for palliative care and glucocorticoid replacement. Nor does it justify Defendants in building a definition of a key patent term upon the absence from that chapter of any reference to use of steroids in cancer-attacking therapy. Incorporation by reference must be clearer than that: "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (citing cases); *see SkinMedica, Inc. v. Histogen*, 727 F.3d 1187, (Fed. Cir. 2013) (observing that textbook which patent purported to incorporate by reference was not helpful to claim construction analysis because the inventor did not "refer with any detailed particularity to the passages in [the textbook]" which the plaintiff claimed supported the plaintiff's proposed construction of a disputed term). The Gilman and Goodman citation fails this test.

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[9] Whether a material is incorporated by reference is a question of law to be determined based on whether a POSA would consider the material incorporated with sufficient particularity. *See AstraZeneca AB v. Hanmi USA, Inc.*, No. CIV.A. 11-760 JAP, 2012 WL 6203602, at *7 (D.N.J. Dec. 12, 2012), *aff'd*, 554 F. App'x 912 (Fed. Cir. 2013).

The plaintiffs argue more generally that the '438 patent never explicitly mentions palliative and glucocorticoid replacement, which are patient-directed therapies. Rather, the patent refers to treatment of cancer, as opposed to patients *with* cancer. It has become a trope, at least of healthcare advertising, that the medical profession treats not the disease but the patient. Such common sentiments have a way of working their way into our prose, but they may reflect nothing more than a manner of speaking. Nevertheless, the plaintiffs' plain language argument has at least some persuasive and corroborative force.

I do not suggest, of course, that the '438 patent explicitly disclaims palliative treatment and glucocorticoid replacement—but it does omit them. How, as a matter of patent language, do the defendants get from the patent's explicit invocation of anti-cancer therapy to the implied inclusion of palliative care and glucocorticoid replacement? Largely by way of the word "includes." Defendants perhaps place more weight on this word than it can bear. Surely "including therapeutic care" does not mean "therapeutic care and everything else." Federal Circuit law has something to say about the interpretation of the word "includes," but before examining that case law, I consider the context of the patent itself.

The plaintiffs are on solid ground in stating that the '438 patent refers throughout only to anti-cancer effects. Some examples:

> Methods and compositions for ***treating cancer*** are described herein. More particularly, the methods for ***treating cancer*** comprise administering a 17α-hydroxylase/C17 20-lyase inhibitor, such as abiraterone acetate (i.e., 3β-acetoxy-17-(3-pyridyl) androsta-5,16-diene), in combination with at least one additional therapeutic agent, such as an anti-cancer agent or a steroid.

('438 patent, Abstract, 1:6–12 (Field of Invention) (emphases added));

> Described herein are methods for ***treating a cancer*** in which a therapeutically effective amount of a 17α-hydroxylase/C17 20-lyase inhibitor, such as abiraterone acetate (i.e., 3β-acetoxy-17-(3-pyridyl) androsta-5,16-diene), is administered ***to a patient, e.g., a patient in***

> ***need thereof***, in combination with a therapeutically effective amount of at least one additional therapeutic agent including, but not limited to, an anti-cancer agent or steroid. ***Such methods can also provide an effective treatment for individuals with a refractory cancer***, including individuals who are currently undergoing a cancer treatment. Therefore, in certain embodiments, the ***method is directed to treating a refractory cancer in a patient***, in which a therapeutically effective amount of 17α-hydroxylase/C17 20-lyase inhibitor is administered to a patient currently receiving an anti-cancer agent.

(*Id.* 2:9–24 (Summary of the Invention) (emphases added));

> The methods described herein for ***treating cancer*** comprise administering to a mammal, preferably a human, a 17α-hydroxylase/C17 20-lyase inhibitor in addition to at least one therapeutic agent, such as an anti-cancer agent or steroid, particularly a glucocorticoid.

(*Id.* 5:9–13) (Detailed Description of the Invention) (emphasis added)).

All 20 claims of the '438 patent contain similar cancer- as opposed to patient- directed language. (*See* '438 patent at cols. 16–17.)

Consider, for example, the juxtaposition of the phrase "methods for treating a cancer" with the phrase "administered to a patient, e.g., a patient in need thereof" in the Summary of the Invention. That juxtaposition, I think, tends to support the plaintiffs' argument, discussed *supra*, that although the medication is "administered" to the patient, the "treating" is directed at the cancer cells. The actual claim is phrased in terms of addressing the cancer, rather than the comfort or other needs of the patient: "A method for the treatment of a prostate cancer in a human . . . ." ('438 patent, 16:16–20 (claim 1).) Likewise, the definition of "treat," "treating," and "treatment" is directed to "a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer." (*Id.* 3:46–50.)

Although neither party mentions it, it is possible to find a contrary, defendant-friendly implication in the above-quoted phrase "[s]uch methods can also provide an effective treatment for individuals with a refractory cancer." That one-off description, however, seems to mean only that the claimed method

is not limited to previously untreated cancer, but also applies to nonresponsive or recurring cancers.

As I say, this language does not conclusively set the boundaries of the terms "treating" and "treatment" or disclaim applications that are not directly therapeutic. But still less does it support the defendants' position that the patent, by silent implication, encompasses patient-based, palliative treatment and glucocorticoid replacement.

Assessing the scope of the disputed terms in view of their most consistent use throughout the specification, I find that Plaintiffs' narrower interpretation is more appropriate. Indeed, Plaintiffs persuasively suggest that one would expect the patentee to have sprinkled at least a few references to pain management and hormone replacement in the specification if that broad construction had been intended. And although it is settled that "federal trial judges must not 'import' or graft limitations from the specification into the claim" where limitations are extraneous to clearly broader claims,[10] it is also the case that a "construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Accordingly, the Federal Circuit has narrowly construed facially broad terms where the specification consistently describes a more limited scope for the term. Plaintiffs cite several examples. *See, e.g., Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1018–19 (Fed. Cir. 2009) (limiting, where "all of the examples described in the specification involve skin wounds," the term "wound" to skin wounds, despite a broader medical dictionary definition); *Edwards Lifesciences LLC v. Cook Inc.*,

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[10] *USHIP Intellectual Props., LLC v. United States*, 98 Fed. Cl. 396, 407, *on reconsideration in part*, 102 Fed. Cl. 326 (2011), and *aff'd*, 714 F.3d 1311 (Fed. Cir. 2013), and *aff'd*, 714 F.3d 1311 (Fed. Cir. 2013); *see also Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.").

582 F.3d 1322, 1329 (Fed. Cir. 2009) (construing "graft" to a particular type of graft where the specification only described those particular devices).

b) Federal Circuit Precedent

For additional assistance in interpreting the word "includes," I turn to Federal Circuit precedent. Defendants identify three cases in which the U.S. Court of Appeals for the Federal Circuit adopted a non-restrictive construction of "includes." Those cases, they say, dictate an open-ended construction of "treatment" and "treating" in this case. I disagree.

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1302–03 (Fed. Cir. 2006), the district court had construed the term "therapeutically effective" in the context of a passage that started "included within the class of humans treatable with products of the invention . . . ." The district court ruled that the invention was limited to products therapeutically effective for the set of patients listed as "included within the class" specified. The Court of Appeals reversed, reasoning: "by using the non-limiting word 'included,' [the patent] suggests some persons, but not all persons, who may benefit from the invention." *Id.* at 1302.

The analogy to the '438 patent is not apt. The *Amgen* patent contained, not just the word "included," but the phrase "included within the class." That phrase plainly and explicitly invokes a "class" that is broader than the particular examples discussed, which are identified as items "within the class." The words "include" or "including", standing alone, do not explicitly invoke a broader class. Unlike the *Amgen* phrase, they do not exclude the possibility of a circumscribed list.[11]

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[11] Additionally, in *Amgen*, the court looked to another phrase in the specification: "It is noteworthy that the absence of in vivo activity for any one or more of the 'EPO products' of the invention is not wholly preclusive of therapeutic utility . . . ." *Id.* Based on this, the court concluded that "therapeutically effective" should not even be construed as limited to products effective in curing disease in humans. Thus, the court had additional reason to broaden the construction of the disputed term. *Id.* at 1302–03.

The other two cases on which Defendants rely—*Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, and *SanDisk Corp. v. Memorex Prod., Inc.*—are less applicable. As the Plaintiffs correctly point out, they stand for "the unremarkable proposition that when a patent claim uses the word 'including,' a device that satisfies the recited claim elements will infringe regardless of whether it contains, additional, unclaimed elements." (Pl. Resp. 9.)[12]

With respect to all three cases, Plaintiffs also draw a distinction between the use of "include" in a patent claim and its use in a patent specification's definitions section. A definition within the specification, meant to define the meaning of a term throughout, cannot be interpreted as an open-ended series of items, or it might become meaningless. (Pl. Br. 9). The point may be overstated; such a definition might usefully identify exemplars so as to create categorical parameters, and in that sense it would not be "meaningless." But there is something to the Plaintiffs' argument. As discussed below, the Court of Appeals for the Federal Circuit has declined to construe the term "including" as open-ended, particularly where, as here, the ordinary claim construction factors point the other way.

In *Lochner Techs., LLC v. Vizio, Inc.*, for example, the patent contained a claim directed to a wireless computer system that disclosed a "portable input-output system *including*" "(1) a wireless transceiver; (2) a user interface; and (3)

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12 *See Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1451 (Fed. Cir. 1997) ("The claim term 'including' is synonymous with 'comprising,' thereby permitting the inclusion of unnamed components."); *SanDisk Corp. v. Memorex Prod., Inc.*,415 F.3d 1278, 1284 (Fed. Cir. 2005) ("As a patent law term of art, 'includes' means 'comprising.' Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations.") (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1344–45 (Fed. Cir.2003) and *Hewlett–Packard Co. v. Repeat–O–Type Stencil Mfg. Corp., Inc.*, 123 F.3d 1445, 1451 (Fed. Cir.1997); *see also Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016) (distinguishing two patent law terms of art and explaining, the term "'consisting of' to set off a patent claim element creates a very strong presumption that that claim element is 'closed' and therefore exclude[s] any elements, steps, or ingredients not specified in the claim," whereas "the transitional term 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." (citations and internal quotation marks omitted)).

a display arrangement." 567 F. App'x 931, 933 (Fed. Cir. 2014) (non-precedential) (emphasis added). Focusing on the word "including," the district court construed the term "input-output system" to be open ended. Based on this construction, the district court later ruled on summary judgment that the patent claims were invalid for lack of written description and for failure to claim what the inventors regarded as their invention. *Id.* at 936–41. On appeal, the Court of Appeals for the Federal Circuit held that the district court had "erred when it assumed that use of the term 'including' somehow trumped consideration of the specification and prosecution history and displaced application of standard claim construction principles." *Id.* at 939. The court explained: "Although 'including' is generally an open-ended term that does not *preclude* additional elements, we have recognized that it does not *require* additional, unspecified elements." *Id.* Critical to the Court of Appeals decision were certain limiting statements made during prosecution, such as the express exclusion of certain features of a full-service computer. Also central to the decision was the written description in the specification, which contained limiting phrases such as "one unit of the computer need only include"; "is composed essentially of three components"; and "[b]ecause of the limited number of components." *Id.* at 934–35. In short, the meaning of "including" was at best context-dependent; it did not signal a broader construction.

Similarly, in *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, the district court construed the term "frame" in a claim reciting "a primary spectacle *frame* for supporting primary lenses *therein,* said primary spectacle frame *including* a middle bridge portion" and "an auxiliary spectacle *frame* for supporting auxiliary lenses *therein,* said auxiliary spectacle frame *including* a middle bridge portion . . ." The district court construed these phrases to mean "an eyeglass device that includes, at least, a bridge and rims." 288 Fed. Appx. 697, 701–02 (Fed. Cir. 2008). The Court of Appeals reversed, agreeing with the plaintiff that a frame without rims could nevertheless infringe: "'Including' is generally an open-ended term that does not preclude additional elements, but 'including' does not require additional, unspecified elements." *Id.* at 702. The

Federal Circuit noted that, in the specification, "[t]he written description never mentions or describes rims, although rims are illustrated in the figures." *Id.*

Although the issues in the cited cases are not otherwise analogous,[13] I find those cases instructive as to the interpretation of "includes." The parties in those cases, like Defendants here, tried to make "includes" do the work of extending the scope of a patent to matters not discussed therein. The Federal Circuit reined in any such interpretation, particularly where it was not supported by the ordinary methods of claim construction. Those holdings lend weight to the argument that "treatment" or "treating" should not be construed to encompass palliative treatment and glucocorticoid replacement where the '438 patent makes no mention of them.

c) The Patent Office's Construction

Defendants argue that the United States Patent and Trademark Office (the "Patent Office") has endorsed their preferred construction. In a 2016 decision to institute an *inter partes* review ("IPR") of the '438 patent, the Patent Office's Patent Trial and Appeal Board ("PTAB") construed the definition of "treatment" in the specification for purposes of reviewing a petition to institute IPR proceedings. The PTAB's construction contained the word "include". *See Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 14 (May 31, 2016); *see also Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 23 (July 21, 2016), at 3 (Resp. Barker Decl. Ex. 1, at 3).

A decision adopting Defendants' interpretation would be relevant, but not dispositive. Because an IPR employs different standards, its findings cannot so easily be transplanted to the context of a *Markman* claim construction process. Indeed, courts have sometimes simply set IPR findings aside: "The decision on claim construction in the inter partes review does not aid this Court, as a district court and the PTO make claim construction decisions under different

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[13] *Lochner,* like this case, involved a would-be infringer's attempt to broaden the interpretation of the patent in aid of an anticipated claim of invalidity. *Aspex* involved an attempt to narrow the scope of the patent to defeat a claim of infringement. For purposes of claim construction, however, those considerations are irrelevant and premature.

standards and parameters." *Shire Dev. LLC v. Amneal Pharm. LLC*, No. 15-2865 (RBK/JS), 2016 WL 4119940, at *4 (D.N.J. Aug. 2, 2016) (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016) (approving "the use of the broadest reasonable construction standard in inter partes review, together with use of an ordinary meaning standard in district court")).

At any rate, the manner in which the issues were presented casts considerable doubt on what exactly the PTAB decided. In that action, Amerigen Pharmaceuticals, Ltd. ("Amerigen") filed a petition to institute IPR seeking to invalidate the '438 patent for obviousness. In its petition, Amerigen proposed definitions of the terms "treat," "treating," and "treatment" as they are defined in the '438 patent specification, but without the word "include". *See* Petition for *Inter Partes* Review at 18, *Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 14 (May 31, 2016). Janssen Oncology, as patent owner, accepted this definition (without "include") for purposes of its response, and hewed closely to the anti-cancer effect in its other proposed definition of a key term—that a "therapeutically effective amount of prednisone" should be construed as "an amount of prednisone effective *for treating cancer*". *See* Patent Owner Preliminary Response, at 18–19, *Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 14 (May 31, 2016) (emphasis added).

In its decision to institute IPR, the PTAB acknowledged that, for purposes of the IPR proceedings, Janssen Oncology had accepted Amerigen's definition of "treat," "treating," and "treatment." Without explanation, however, the PTAB construed the terms for purposes of the IPR proceedings *with* the word "include". *See Amerigen Pharms. Ltd.*, Paper 14 at 5, 7, 19. The PTAB agreed with Janssen Oncology's construction of "therapeutically effective amount of prednisone." *Id.* at 6–7. The PTAB then granted Amerigen's petition to institute IPR, explaining that it did so on the basis of Amerigen's "reasonable likelihood of prevailing with respect to its challenge of claims 1-20 of the '438 patent" for obviousness over prior art. *Id.*

Janssen Oncology requested reconsideration of the IPR decision, maintaining that it was instituted in error; Amerigen, it argued, failed to meet

its threshold burden of demonstrating it was likely to show at trial that the prior art teaches or suggests "the claimed co-administration including a 'therapeutically effective amount of abiraterone acetate,' and, separately, 'an amount of prednisone effective for treating [*i.e.*, having an *anti-cancer effect on*] prostate cancer.'" Request for Reconsideration, at 6, *Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 14 (May 31, 2016) (alteration and emphasis in original).

The PTAB denied Janssen Oncology's rehearing request, explaining:

> Although Patent Owner does not advocate for a new claim construction in its Request for Rehearing, its arguments are based on a construction that we have not adopted, namely, that "treating" must mean "having an anti-cancer effect on." *Id.* A Request for Rehearing is not an opportunity to present a new argument about claim construction, notwithstanding its framing as a matter that we addressed in our Decision to Institute.

Amerigen Pharms. Ltd. v. Janssen Oncology, Inc., IPR2016-00286, Paper 23 (July 21, 2016), at 3–4 (Resp. Barker Decl. Ex. 1, at 3–4). Thus, the PTAB never addressed head-on whether "treating" or "treatment" should be construed narrowly or broadly; rather, the PATB enforced a procedural bar, ruling that the time to construe claim terms had passed.[14]

2. Prosecution History

I next consider the prosecution history. Prosecution history, which represents an ongoing negotiation history between the applicant and the Patent Office, ranks lower in the *Vitronics* interpretation hierarchy than, *e.g.*, the plain language of the patent. *See Phillips*, 415 F.3d at 1316; *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1379-80 (Fed. Cir. 2005)). Nevertheless, it has relevance.

Defendants point out that the Patent Office rejected on obviousness grounds certain pending claims that were identical to claim 1. That rejection

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[14] The PTAB also rejected Janssen Oncology's argument that a rehearing was necessary to correct the PTAB's failure to consider the Patent Office's "prior determination of commercial success and Petitioner's admission of unexpected results"; the PTAB determined that it had sufficiently taken these considerations into account. *Id.* at 5.

rested on two prior-art articles, one of which—Tannock et al. (1996) ("Tannock")—investigated the use of prednisone in treating refractory prostate cancer, and specifically looked at "end points of palliation." (*See* Def. Br.1 13–16 (quoting Barker Decl. Ex. 6 at 1756).) In arguing that the pending claims were not obvious, the inventor/applicants distinguished Tannock on the basis that Tannock disclosed the use of prednisone with the chemotherapy drug mitoxantrone specifically, as opposed to prednisone with any other drug such as abiraterone acetate, to treat prostate cancer. (*Id.*; *see* Barker Decl. Ex. 7 at 7–13.) Defendants contend that, if the applicants were not claiming palliative treatment, they would have sought to distinguish Tannock on that basis as well. But, they did not. And from that inference, Defendants draw the further inference that Plaintiffs must have understood that they were claiming methods of "treatment" of prostate cancer that encompassed the administration of prednisone for the purpose of pain relief/palliation. (*See* Def. Br. 14–16.)

It is possible simply to find Defendants' logic here strained. Plaintiffs, however, attack the premise of Defendants' patent prosecution argument. Tannock was distinguished, they say, because it concerns cytotoxic chemotherapy—an entirely different type of treatment from the hormonal therapies claimed in the '438 patient—and because it failed to show any improvement in patient survival or PSA levels (in indicator of prostate tumor growth or progression). (Pl. Resp. 10, 13–15). During prosecution, the applicants discussed extensively the unexpected results that the '438 patent invention produces—namely, that administration of abiraterone acetate together with prednisone has antitumor effects. (*Id.*)

The most pertinent case Defendants cite in support of their prosecution history argument is *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.* There, the Court of Appeals for the Federal Circuit found that a patent's prosecution history supported a construction of the term "dispensing" that was broader than the limited construction—"direct dispensing"—that was being proposed. 473 F.3d 1173, 1182–83 (Fed. Cir. 2006). The court credited the plaintiffs'

argument that during prosecution, the inventors had not relied on that narrow interpretation, which would have been a natural basis to distinguish prior art. *Id.*[15] That argument, so far, is analogous to Defendants' argument here. But in *Ventana*, the court also looked to direct evidence that the examiner had adopted the broader understanding of the claim.[16] *Id.* at 1183 ("the examiner observed that 'the process as claimed can be practiced by another materially different apparatus or by hand, such as a manual pipette means.' This statement shows that the patent examiner did not consider the 'dispensing' claim term to be limited to the 'direct dispensing' embodiment disclosed in the specification."). And the court was also concerned that construing the term narrowly, in the context of that particular patent, would run afoul of the Federal Circuit's previous warnings against confining claims to disclosed embodiments. *Id.* at 1181. Finally, the *Ventana* court noted that each claim did not cover every feature disclosed in the patent's specification, and held that "[w]hen the claim addresses only some of the features disclosed in the

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15 Specifically, "the inventors did not rely on "direct dispensing" as a distinction between the claims at issue . . . and the prior art. Instead, in response to rejections over the prior art, the inventors limited their arguments to the ability of the claimed inventions to address the shortcomings of [the prior art]." *Id.* at 1183.

16 This was also the case in *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc.*, another case on which Defendants rely (*see* Def. Resp. 15-16), in which the Court of Appeals noted that the applicants "did not attempt to change the Examiner's understanding of the invention." 482 F. Supp. 2d 478, 497-98 (D.N.J. 2007), *aff'd in part, vacated in part sub nom. Ortho-McNeil Pharm., Inc. v. Teva Pharm. Indus., Ltd.*, 344 F. App'x 595 (Fed. Cir. 2009), *vacated* (Oct. 20, 2009). There, a statement by the examiner very clearly indicated an understanding that aligned with the plaintiff's construction. *Id.* Here, I am not so convinced that the examiner's finding of obviousness necessarily implied that the invention disclosed in the '438 patent's parent application encompassed palliative care; it is quite plausible that the examiner only considered it obvious to combine abiraterone and prednisone for the direct treatment of cancer. (*See* Barker Decl. Ex. 5 (Sept. 24, 2010 Office Action filed in U.S. Patent Application No 11/844,440) at 3 ("It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer.")).

specification, it is improper to limit the claim to other, unclaimed features." *Id.* at 1181.

In short, the ordinary tools of claim construction dictated a result in *Ventana* that was corroborated by the prosecution history. Here, by contrast, as discussed *supra*, a reading of the specification points the other way; it favors Plaintiffs' construction over Defendants'.

> "[T]here are, of course, situations in which what an attorney says or does during prosecution may be held against a patentee on the theory of estoppel. For example, when a patentee attempts to *expand* the literal meaning of a claim under the patent law doctrine of equivalents and the prosecution history shows that the expanded scope would be inclusive of subject matter the attorney had represented to the examiner was *not* intended to be included in order to get the claim allowed, the patentee may be estopped to contend otherwise."

Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989). And of course an applicant's explicit disclaimer of an interpretation during patent prosecution may be very relevant. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution. Accordingly, where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." (citations and internal quotation marks omitted)).

But this is not such a situation. The inventors did not downplay the scope of their claims to win approval, only to exaggerate them later. Nor is the applicants' silence as to palliative care one of those silences that speaks louder than words; I am not persuaded that an applicant who espoused a narrow interpretation would surely have said so in that situation. I find the logic of Defendants' argument from silence to be attenuated and strained.

3. Extrinsic Evidence

Finally, I consider extrinsic evidence, which occupies the bottom rung of the *Vitronics* ladder of relevance. Essentially, the defendants resort to outside sources for definitions of terms as a POSA would have understood them.

First, Defendants focus on the word "management" in the phrase "management or control of a tumor or primary, regional or metastatic cancer cells, or tissue." They claim that "a POSA would understand that the 'management' of prostate cancer in a human includes providing benefits such as pain relief and glucocorticoid replacement therapy (*i.e.*, palliative and supportive treatment)." (*See* Def. Br. 16–18.) Defendants submit the declaration of their expert, Dr. John P. Fruehauf, Director of Clinical Pharmacology and Developmental Therapeutics at the University of California at Irvine, to support that proposition. (*See* Def. Br. 10 n.7; Def. Resp. 5; Fruehauf Decl. ¶¶ 25, 28 33.) Specifically, Dr. Fruehauf opines: "a POSA would understand [that "management"] includes addressing other conditions associated with the prostate cancer (*e.g.*, pain and steroid deficiency) that the patient may experience." (Fruehauf Decl. ¶ 28.)

Plaintiffs do not submit any expert rebuttal of Dr. Fruehauf's declaration. They fall back on their plain-meaning argument that Dr. Fruehauf's opinion on the meaning of "management" would improperly equate "tumor" with "patient," contrary to the approach of the patent language itself. *See* Section II.B.1.(a), *supra*. Dr. Fruehauf's deposition testimony, they say, confirms that he conflated the two: "you don't treat a tumor; we treat a person and [the patient is] the body that the tumor exists within." (Barker Resp. Decl. Ex. 1 at 156:23-157:2.) I have already dealt with this argument above.[17]

Dr. Fruehauf also cites certain extrinsic sources and authorities. One is Stedman's Medical Dictionary, which defines "treatment" as "medical or

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[17] The other opinions expressed in Dr. Fruehauf's expert declaration essentially mirror the arguments Defendants make in their briefing, also discussed above. Dr. Fruehauf relies, for example, on the Goodman and Gilman citation in the specification, which I have already discussed.

surgical management of a patient," and provides definitions for sub-categories of "treatment", including "active treatment" and "palliative treatment". (*See* Fruehauf Decl. ¶ 33; Def. Br. 16–17; Barker Decl. Ex. 8.) It is clear from the context, however, that use of the term "treatment" does not necessarily imply that any particular one of the sub-categories is present. Indeed, as Plaintiffs point out, the dictionary "lists no fewer than thirty-one sub-categories" of treatment; many, perhaps most, if read into the '438 patent, would render it absurd—"root canal treatment," "moral treatment," and "shock treatment," for example. (*See* Pl. Resp. 16; Barker Decl. Ex. 8.) Because there is no principled basis to cherry-pick the palliative sub-category and read it into the definition of treatment, the Stedman's definition does not appreciably advance the argument.[18]

Also cited by Dr. Fruehauf are articles co-authored by one of the '438 patent's inventors, Dr. Arie S. Belldegrun. One refers to "the need for novel agents to treat prostate cancer," and concludes that "[t]here is an urgent need for new agents that provide palliation and improve survival." (Barker Decl., Ex. 9). These statements do not appear in the same sentence; nor do they state or imply that the word "treatment" implies palliation. Another article by Dr. Belldegrun refers to "pain relief" as a type of "clinical benefit" and "palliation" as a "[t]rial end point[] considered important." (Barker Decl., Ex. 10.) Again, no one doubts the importance of pain management. But this falls even shorter of providing a clear definition of "treatment" or "treating". In short, the statements in both articles are taken out of context, and in any event fail to elucidate how the term "treatment" should be interpreted in the '438 patent.[19]

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[18] The Defendants and Dr. Fruehauf also highlight that Stedman's defines "active treatment" as "a therapeutic substance or course intended to ameliorate the basic disease problem, as opposed to supportive or palliative," (Def. Br. 16–17; Fruehauf Decl. ¶ 33), but give no sound reason why "treatment" necessarily encompasses both active and palliative treatment, or why a POSA would understand it to do so.

[19] To the extent the articles might be cited to cast light on Dr. Belldegrun's contemporaneous subjective state of mind, they are irrelevant. *See N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1578 (Fed. Cir. 1993) ("A patent is to be interpreted by what it states rather than by what the inventor wrote in a scientific publication.")); *Markman*, 52 F.3d at 985 ("The subjective intent of the inventor when he used a

Finally, at the *Markman* hearing, counsel for Defendants submitted an additional piece of extrinsic evidence: the definition of the word "include" in Black's Law Dictionary. The plain meaning of the word "include," according to Black's, is "to contain as a part of something." *See* INCLUDE, Black's Law Dictionary (10th ed. 2014). "Because dictionaries . . . endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005). However, "extrinsic evidence may never conflict with intrinsic evidence, because courts 'have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms.'" *Alberta Telecomms. Res. Ctr. v. AT & T Corp.*, No. CIV.A. 09-3883 PGS, 2012 WL 3286053, at *2 (D.N.J. Aug. 10, 2012) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005)).

I give the Black's citation little weight. Black's is a dictionary of terms as used in legal opinions, not patents. To the extent it conflicts with the higher-priority claim construction evidence, it is unconvincing. And this extrinsic evidence of course must be given less weight than the intrinsic evidence that is now before me. *See id.*

The language of the specification, the context in which both the disputed claim terms ("treating" and "treatment") and the disputed definitional terms ("include" and "management") appear, and the lack of significant textual support for Defendants' competing interpretation, all lead me to accept Plaintiffs' proposed construction.

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particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history).")).

III. CONCLUSION

For the foregoing reasons, I construe the disputed terms of the '438 patent as follows:

(Claim 1) *Treatment/treating* means the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer.

KEVIN MCNULTY
United States District Judge

DATED: November 10, 2016